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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,834	06/27/2003	Viola Vogel	91-02	4707

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GREENLEE WINNER AND SULLIVAN P C
4875 PEARL EAST CIRCLE
SUITE 200
BOULDER, CO 80301

EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

10/607,834

Applicant(s)

VOGEL ET AL.

Examiner

Ginny Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-85 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims 1-85 are pending.

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. At paragraph [0257] a hyperlink is recited; it should be removed.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-42, and 85 are drawn to a plurality of independent and distinct methods of **changing the binding strength** between an adhesion molecule and its binding ligand, classified in class 422, subclass 186.
 - II. Claims 43-50, drawn to a plurality of methods of **removing a target particle** from a fluid utilizing both an adhesion molecule, a ligand, a binding agent for the target and a removing agent, classified in class 435, subclass 272.
 - III. Claims 47-48 and 51-52, 57, drawn to a plurality of **methods of separating** first and second binding ligands from each other with an adhesion and removing agent, as well as methods drawn to a plurality of methods of selectively removing a first ligand in a fluid that comprises a second ligand, an adhesion for the first ligand and a removing agent classified in class 530, subclass 344.
 - IV. Claims 56, drawn to a **method of selectively releasing** a ligand, classified in class 424, subclass 461.

- V. Claims 58-62 63, drawn a plurality of methods that measure the rate of flow of a fluid by adding both adhesions and ligands to the fluid, classified in class 435, subclass 7.3.
- VI. Claims 53-55, drawn to a plurality of **fluidic devices** that evidence a plurality of adhesins attached thereto, classified in class 422, subclass 68.1.
- VII. Claims 64-66, drawn to a plurality of bond **stress activated values** for controlling a fluid flow rate in a channel and comprises both adhesions and ligands and the adhesive system, classified in class 422, subclass 105.
- VIII. Claims (67-70, 72 products), 71, 73, drawn to a plurality of **adhesive systems** and method of making the adhesive system and a method of using by modifying the viscosity of a fluid, classified in class 424, subclass 407.
- IX. Claims 76-78, drawn to **antibodies** that will bind to FimH, classified in class 530, subclass 388.2.
- X. Claims 74-75, drawn to a plurality of methods of using any one of a plurality of antibodies that bind to an adhesion in a location other than where the ligand binds, thus interfering with ligand binding, classified in class 435, subclass 7.93
antibodies **competitive inhibition of ligand**.
- XI. Claims 79-80 and 84, 81-83 drawn to a plurality of compositions that comprise **FimH polypeptides**, and a method of making engineered forms of FimH classified in class 424, subclass 242.1.

The inventions are distinct, each from the other because of the following reasons:

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2. Inventions Groups (VI or VII (devices)) and Groups (I, II, III, IV, V or VIII (methods of use)) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product, wherein the devices can be used to selective release a ligand, to remove a target particle, to separate ligands, or measure flow rates of a fluid, or to modify the viscosity of a fluid.

3. Inventions IX and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product, wherein the antibodies can serve as diagnostic agents, an affinity reagent in the purification of FimH antigen and in methods of passive immunization against E.coli infection.

4. Inventions IX (antibodies directed against FimH) and XI (FimH polypeptides) are related as subcombinations disclosed as usable together (diagnostic assay) in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination the antibodies have separate utility such as a reagent in a method of competitive inhibition for identifying ligands that are inhibited by the antibody binding to a

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location other than the ligand-binding site, thus identifying therapeutic antibodies. See MPEP § 806.05(d).

5. Inventions XI (FimH adhesion) and (VI or VII (devices that comprise adhesion) are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination FimH has separate utility such as an immunogenic composition for the generation of antibodies. See MPEP § 806.05(d).

6. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

7. This application contains claims directed to the following patentably distinct species:

Groups I-VIII and X are directed to of methods that utilize one of a plurality adhesion molecules with or without (depending on the Group) one of a plurality of ligand molecules:

8. Select increase or decrease change in bond stress (if applicable to Group).

9. Select mode of change (if applicable to Group):

- a. Electric current
- b. Shear force
- c. Tensile force
- d. Genetically engineered
- e. Modified by truncation

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Select one **FABSDAM** (If applicable to group)

- Adhesins
 - FimH polypeptide (claims 8-9, or 10 or) or SEQ ID NO 4 or 5 or 6 or 7 or SEQ ID NO 8 or 9 or 10 or 11 or 12 (defined in claims 79-80 and 84)
 - FimH variants (claim 12, claim 15)
 - FimH mutants (claim 11, 13, 14,)
 - FimH truncated
 - lectin binding domain (claim 8)
 - peptide (SEQ ID NO 1, aa 25-31) (defined in claims 79-80 and 84)
 - peptide (SEQ ID NO 2, aa 110-123) (defined in claims 79-80 and 84)
 - peptide (SEQ ID NO 3, aa 150-160) (defined in claims 79-80 and 84)
- Selectins
- Integrins
- Cadherins
- Immunoglobulin superfamily cell adhesion molecules
- Syndecans

Select one **FABSDB-L: free or attached to a particle (if applicable to Group):**

- Mannose (claim 16-17)
 - Monomannose
 - Trimannose
 - oligomannose
- Fructose (claim 16)

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If Ligand attached to a particle is selected, then an additional selection of type of particle/solid surface is requested:

- Bacterial pili
- Naturally occurring isolated molecules
- Synthetic molecules
- Proteins
- Polypeptides
- Organelles
- Prokaryotic cells
- Eukaryotic cells
- Viruses
- Organisms
- Nanoparticles
- Microbeads
- Microparticles
- Cell membranes
- Devise surfaces
 - Cylinders (claim 32,36)
 - Channel (fluid containing channel, claim 37)
 - With exit and bypass ports (claim 42)
- Synthetic substrate surfaces

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10. Group XI: is directed to a plurality of FimH polypeptides that structurally and functionally differ one from the other based upon differing SEQ ID NO. Applicant is requested to select a single SEQ ID NO product if Group XI is selected:

- FimH polypeptide : SEQ ID NO 4 or SEQ ID NO 5 or SEQ ID NO 6 or SEQ ID NO 7 or SEQ ID NO 8 or SEQ ID NO 9 or SEQ ID NO 10 or SEQ ID NO 11 or SEQ ID NO 12
- FimH variants (E.coli strain f18 or j96)
- FimH mutants (specific locations for mutations, positions 154, 155, 156 32 or 124)
- FimH truncated
 - lectin binding domain (claim 8)
 - peptide (SEQ ID NO 1, aa 25-31) (defined in claims 79-80 and 84)
 - peptide (SEQ ID NO 2, aa 110-123) (defined in claims 79-80 and 84)
 - peptide (SEQ ID NO 3, aa 150-160) (defined in claims 79-80 and 84)

11. The species are independent or distinct because the reagents are structurally and functionally independent and distinct based upon differing amino acid sequences, and the ligands to which that will bind; each reagent evidencing a different structure, function and biological/chemical effect.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Ochiai/Brouwer Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See A Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp
August 28, 2006


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600